Abstracts of the HIV Drug Therapy Glasgow Congress 2014
Lanzafame M et al. *Journal of the International AIDS Society* 2014, **17(Suppl 3)**:19822
http://www.jiasociety.org/index.php/jias/article/view/19822 | http://dx.doi.org/10.7448/IAS.17.4.19822

JIAS Journal of the International AIDS Society

Poster Sessions – Abstract P290

Efficacy of a reduced dose of DARUNAVIR/RTV in a cohort of antiretroviral-naïve and experienced HIV-infected patients: a medium-term follow-up.

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Background: The currently approved dose of darunavir/ritonavir is 800/100 mg once daily for PI-naïve patients, and 600/100 mg twice daily for PI-pretreated patients. However, in DRV-sensitive patients at baseline in the POWER 1/2 trials, similar rates of HIV RNA suppression (1 log reduction) were achieved with doses ranging from 400/100 mg once daily to 600/100 mg twice daily. In previously virologically suppressed patients, a reduced dose of DRV (600/100 QD) is non-inferior to the standard dose (800 mg QD)[1] and DRV concentrations in plasma and CSF are similar in patients receiving the above different doses [1,2].
Methods: Twelve treatment-naïve patients were started on darunavir/ritonavir 600/100mg once daily, with TDF/FTC (8) or ABC/3TC (4). Seven patients were switched to darunavir/ritonavir 600/100 mg once daily, with TDF/FTC (2), ABC/3TC (2), NVP (1), AZT/3TC (1). One was on monotherapy with DRV. Seven treatment-experienced patients were switched to darunavir/ritonavir 600/100 mg once daily, with TDF/FTC (5), ABC/3TC (1), RAL (1).
Results: Of the 12 naïve patients (mean baseline HIV RNA 134,024 log10 copies/mL, range 4,256-397,932), 11 had HIV RNA <20 c/mL after a mean 27.4 months of follow-up (range 12–33). Mean PK level was 2,920 ng/mL (1,268–4,562). One patient had virological failure after 14 months (HIV RNA 39,300 copies/mL); no mutations were detected and after introduction of DRV/r 600 mg b.i.d., he returned aviremic. All switched patients maintained HIV RNA suppression (<20 c/mL) for a mean of 32.8 months (range 21-54). PK level was available for one patient only (Ctrough 3,442 ng/mL). Of the treatment-experienced patients (mean baseline HIV RNA 24,167 log10 copies/mL, range 112–111,426), five maintained HIV RNA suppression for a mean of 46.2 months (range 31–67). One patient interrupted HAART for three months and then restarted it, the latest HIV RNA level being 628 copies/mL after five weeks of therapy. One patient failed after 42 months (HIV RNA 3,930 copies/mL); after intensification (DRV/r 600 twice daily), he returned aviremic. PK levels were available for three patients (mean 2,502 ng/mL; range 844–4,518).
Conclusions: In this pilot study of 26 patients, use of DRV/r at 600/100 mg OD dose led to sustained HIV RNA suppression in 23 patients with acceptable PK exposures to DRV. Large non-inferiority trials are warranted to establish its efficacy.

References

1. Molto J, Valle M, Ferrer E, Curran A, Santos JR, Di Yacovo S, et al. Reduced darunavir dose is as effective in maintaining HIV suppression as the standard dose in virologically suppressed HIV-infected patients. 15th Intl Workshop Clinical Pharm HIV Therapy. Washington DC, 19–21 May 2014 (abs O_02).
2. Di Yacovo S, Molto J, Ferrer E, Curran A, Back D, Clotet B, et al. CSF viral load and darunavir concentrations in patients receiving DRV/r 600/100 mg or 800/100 mg once daily (OD) plus two nucleosides. 15th Intl Workshop Clinical Pharm HIV Therapy. Washington DC, 19–21 May 2014 (abs P_46).

Published 2 November 2014